



⑫ **EUROPEAN PATENT APPLICATION**

⑲ Application number: **91500092.1**

⑤① Int. Cl.5: **A61J 1/14**

⑳ Date of filing: **08.08.91**

③① Priority: **17.01.91 ES 9100145 U**

④③ Date of publication of application:
22.07.92 Bulletin 92/30

⑥④ Designated Contracting States:
AT BE CH DE DK FR GB GR IT LI LU NL SE

⑦① Applicant: **INSTITUTO DE BIOLOGIA Y
 SUEROTERAPIA, S.A.**
Calle Antonio Lopez, 111
E-28026 Madrid(ES)

⑦② Inventor: **Faraco Munoz, Francisco**
Melilla, 8
E-28005 Madrid(ES)

Inventor: **Moreno de la Guerra, Miguel Angel**
Pedro Laborde, 11
E-28038 Madrid(ES)

Inventor: **Frias Garcia, Gregorio**
Rio Bullaque, 6
E-28034 Madrid(ES)

Inventor: **Sandoval Balcazar, Carlos Manuel**
Abtao, 44
E-28007 Madrid(ES)

⑦④ Representative: **Elzaburu Marquez, Alberto et
 al**
Sres. Elzaburu Industrial Property Attorneys
Miguel Angel, 21
E-28010 Madrid(ES)

⑤④ **Access device for flexible containers.**

⑤⑦ An access device for flexible containers (18) is described, formed by an injected piece and two elastomeric pieces (6,7), in which the latter are adapted to the punch of an administration equipment and/or an addition needle by means of the formation of an hydraulic closure, the elastomeric pieces (6,7) being engaged to the injected piece through bulges (4,5) located around some access openings (2,3).

The access device is particularly suitable for flexible containers (18) destined to contain large-volume parenteral solutions.

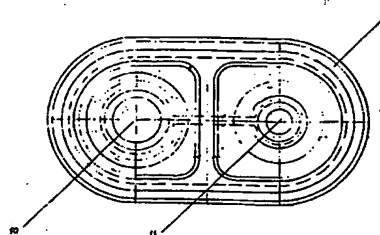
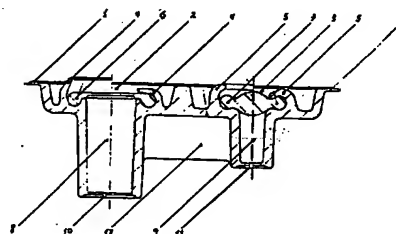


FIG. 1

The present invention, as expressed in the title of this Specification, comprises an external device attached to flexible containers, for the extraction and/or addition of liquids contained, or to be contained, in said containers; being sterilizable and of particular application for large-volume parenteral solutions.

The devices currently available are characterized in being formed with an elaborated edge, on manufacturing the flexible container, clamping therein an elastomeric member, included in a tubular piece of material such as polyethylene or polyvinylchloride, maintaining sterility with an adhesive cover, or with a strip of polyvinylchloride which is torn off at the time of use; they have the drawback of several materials being in contact with the contained solutions, the elastomer itself, the polyethylene or polyvinylchloride of the member containing the elastomer and the material which the flexible container is composed of, which can be polyvinylchloride, polyolefines, polyamides, etc., and their adhesives and further additives, which involves an extraction of products of those materials in a greater variety, undesired due to the problems they can promote on administering the solution; in other cases they are external systems attached to flexible multilayer containers, which layers are joined by adhesives which can migrate to the contained solution, likewise an undesired effect for administration of the contained liquid.

The importance of these phenomena has been dealt with in various Pharmacopoeias which, to allow the use of a material for large-volume parenteral solutions, force one to determine the absence or presence, under certain limits, of this type of transfer to the contained solutions.

The object of the invention relies on achieving an outer device to the container, that would contain the necessary elastomers to serve as liquid retaining joint, around the punches of the administration equipments and needles for addition and/or extraction, avoiding leakages through dripping; which, as safety measure, serve to confirm that the container has not been tampered with; being attached to the outer surface of single- or multi-layer coextruded flexible containers, without the need for adhesives, manufactured from different types of materials but kept in contact with the polyolefines solution to reduce transfer; this attachment being carried out by physical means such as heat, ultrasound, or high frequency welding, without using adhesives, the arrangement of solution, container and access device being susceptible to sterilization at temperatures between 100 C and 130 C, with wet heat in equipments with vapor or superheated water.

To improve understanding of this Specification, and forming an integral part of the same, a series of figures is attached wherein, by way of illustration

and non-limitative, various suitable examples of this invention are represented, as functionally equivalent embodiments of the same. Referring to the numerals indicated in the figures, one can see how the device has a flat and flexible zone (1), to attach the device to the outer part of the flexible container by heat, ultrasound or high frequency welding without the need to use adhesives, on the piece being manufactured with materials identical to those of the multilayer of the container: polyolefine homopolymers, polyolefine copolymers, natural and synthetic elastomers, polyamides and combinations, modifications or special arrangements thereof; in the lower side this zone has two openings (2) and (3) formed at the time of injection, thereby avoiding the particles that can be produced if carried out by piercing; such holes serve to allow entry or release of the liquid once the outside of the container has been pierced.

Around both holes, completely surrounding them, there are bulges (4) and (5) formed with the injection material which on being injected, are arranged perpendicularly to the welding plane (1), to allow insertion of the elastomeric pieces into their housing; once the pieces are inserted, the bulges are deformed by means of friction or heat, so that the end of the bulges clamp the elastomeric pieces, to avoid driving them on introducing the point of the administration equipment or the addition or extraction needle.

As mentioned in the above paragraph, in some housings of suitable size, there are two elastomeric pieces (6) and (7) which are inserted into the openings (2) and (3) before deforming the bulges (4) and (5); one of the elastomeric pieces (6) serves for effecting the closure around the punch of the administration equipment and can be solid, in which case the punch should pierce it, or in O-ring shape with circular cross-section, in which case the ring engages the outside of the punch; the other elastomeric piece (7) serves to carry out the closure around the addition or extraction needle, while piercing and self-sealing is being effected when the needle is withdrawn; these pieces can be manufactured by moulds of different materials such as virgin gum, butyl chloride, butyl bromide, EPDM, silicone gum and other elastomers, as well as by the injection of thermoplastic elastomers; in all the cases they should be compatible with large-volume solutions and with sterilization at temperatures between 100 c and 130 C with wet heat.

Following the housing of the elastomeric pieces the device narrows inside, to avoid said pieces (8 and 9) moving, in tube shape and suitable sizes, in the one case, to the punch of the administration equipment (8) and, in the other case, to that of the addition or extraction needle (9). These tubular shapes end in flat zones which serve as seal to

guarantee the container has not been tampered with, which can be planes (10) and (11) parallel to the welding plane (1), in which case the opening is effected by piercing with the punch or with the needle, or planes (12) and (13) perpendicular to the welding plane (1) in suitable shape to hold such planes with the fingers, pincers and pliers or other similar instrument, and by twisting leaving exposed the tubular accesses to the elastomeric pieces, aided by respective perimetral recesses (14) and (15) which facilitate the tearing.

On the outside the tubular piece (9) adapted to the addition or extraction needle may have injected shapes (16) of male screws of the luer type, luer-lock, record or any other suitable screw or figure for attaching accessories, that allow facilitating the addition or extraction of liquids or solutions, once the security seal (11) or (13) is removed.

To give the arrangement greater rigidity and facilitate handling during piercing the device and the container, the device may comprise a flat zone (17) perpendicular to the welding plane (1) joining the two tubular access shapes (8) and (9).

Figure 1 represents the plant and an elevational section of a device in which the bulges (4) and (5) appear undeformed in the left-hand part of the elastomeric pieces (6) and (7) and deformed in the right-hand side; it is characterized by having both solid elastomeric pieces and the flat zones (10) and (11) of the security seal parallel to the welding plane (1), and the length of the tubular shape (9) suitable for all kinds of needles.

Figure 2 represents an elevational section of a device in which the bulges (4) and (5) appear undeformed in the left-hand part of the elastomeric pieces (6) and (7) and deformed in the right-hand part; it is characterized by having both solid elastomeric pieces, the flat zones (12) and (13) of the security seal perpendicular to the welding plane (1) and the length of the tubular shape (9) suitable for all kinds of needles.

Figure 3 represents an elevational section of a device in which the bulges (4) and (5) appear undeformed in the left-hand part of the elastomeric pieces (6) and (7) and deformed in the right-hand side; it is characterized by having the elastomeric piece (6) for the closure at the punch of the administration equipment in O-ring shape and the solid elastomeric piece (7), the flat zones (12) and (13) of the security seal perpendicular to the welding plane (1) and the length of the tubular shape (9) suitable for long needles.

Figure 4 represents an elevational section of a device in which the bulges (4) and (5) appear as injected, i.e., undeformed; the elastomeric pieces (6) and (7) are the same as in Figure 3, one being solid and the other one being an O-ring, the flat zones (12) and (13) of the security seal perpen-

dicular to the welding plane (1), the length of the tubular shape (9) suitable for long needles and the length of the tubular shape (8) suitable for short punches.

5 Figure 5 represents an elevational section of a device of similar characteristics to that of figure 4, with the difference that the lengths of the tubular shapes (8) and (9) are suitable for every kind of punch and needle.

10 Figure 6 represents the plant and an elevational section of a device with characteristics similar to those of Figure 5, in which a male screw (16) has been represented to allow attaching the accessories for addition or extraction, once the security seal (13) is removed.

15 Figure 7 represents top views and side sections of the elastomeric pieces (6) and (7).

Figure 8 represents a side view of a device according to the invention, attached to a flexible container (18).

Claims

1. Access device for flexible containers adapted to contain large-volume parenteral solutions, formed by an injected piece and two elastomeric ones, characterized in that the elastomeric pieces, (6, 7) solid or in O-ring shape, are adapted to the punch of the administration equipment (8) and/or the addition needle (9), producing an hydraulic closure, the elastomeric pieces (6, 7) being attached to the injected piece through the mechanical and/or thermic formation of injected bulges (4, 5) located around the access openings.
2. Device according to claim 1, characterized in that the injected piece is provided with a flat zone (17) with which it is attached to the flexible container.
3. Device according to the preceding claims, characterized by having two tubular shapes (8, 9) parallel to one another and perpendicular to the join plane, one adapted to the dimensions of the punches of the administration equipment (8) and the other adapted to the dimensions of the needle (9) for addition and/or extraction of liquids from the container.
4. Device according to the preceding claims, characterized in that the two tubular shapes (8, 9) are closed by flat security seal zones (12, 13), which once broken allow extraction or addition of liquids or solutions.
5. Device according to the preceding claims, characterized in that the security seal (12, 13)

parallel to the welding zone opens by perforation with the punch of the administration equipment (8) or with the addition or extraction needle (9).

5

6. Device according to the preceding claims, characterized in that the security seal (12, 13) perpendicular to the join zone opens by tearing the flat piece by twisting, facilitated by a suitable recess in the tubular shape.

10

7. Device according to the preceding claims, characterized in that it has male screws (16) of different pitch or other type of suitable shape for attaching accessories to facilitate the addition or extraction of liquids or solutions.

15

20

25

30

35

40

45

50

55

4

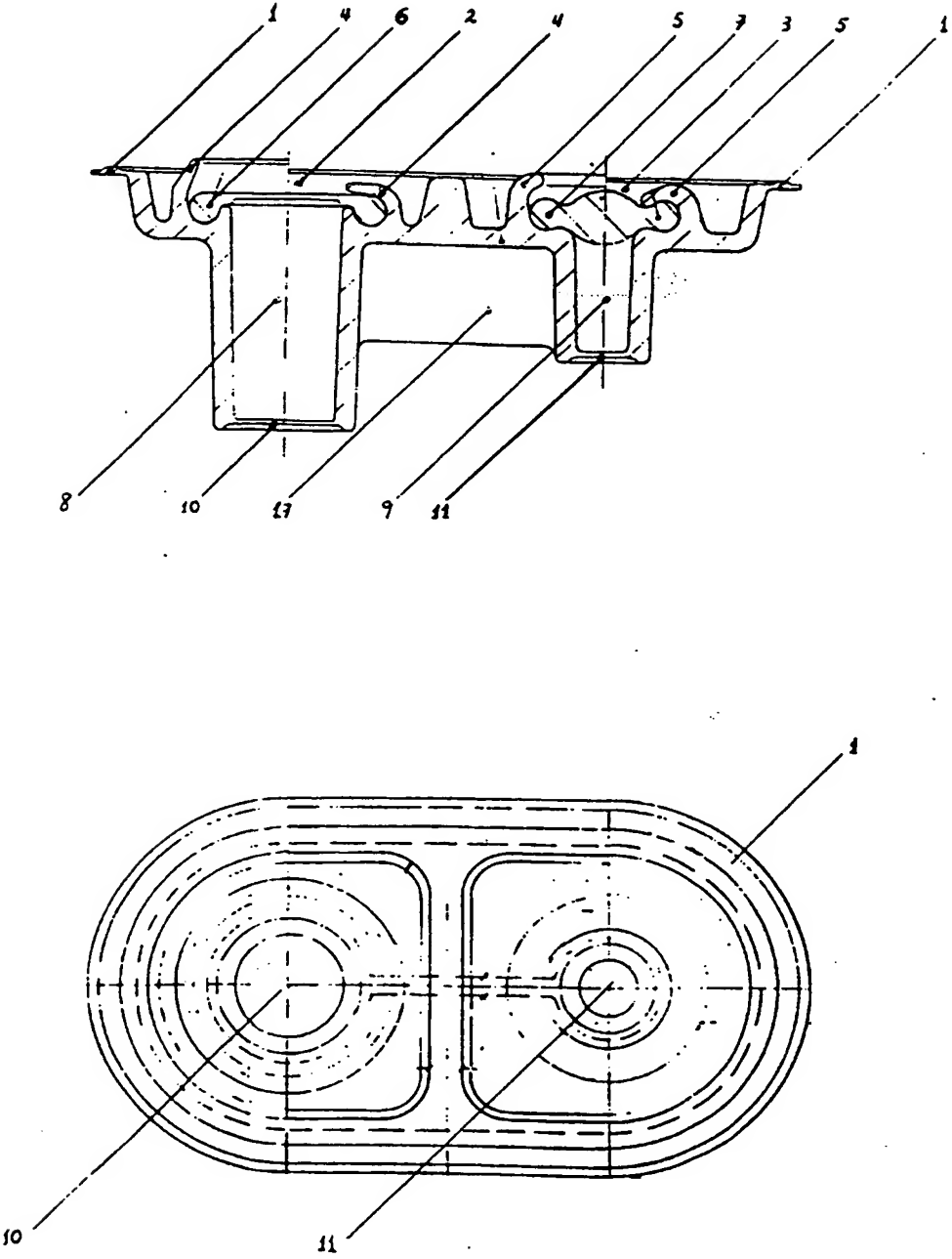


FIG. 1

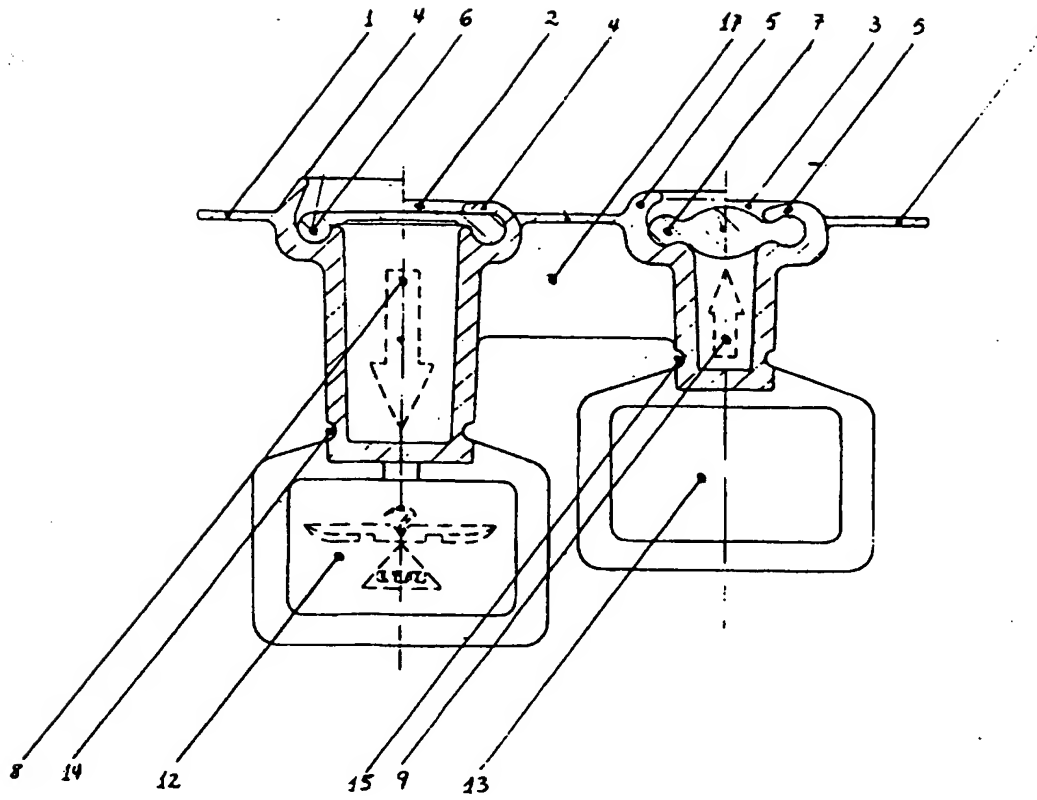


FIG. 2

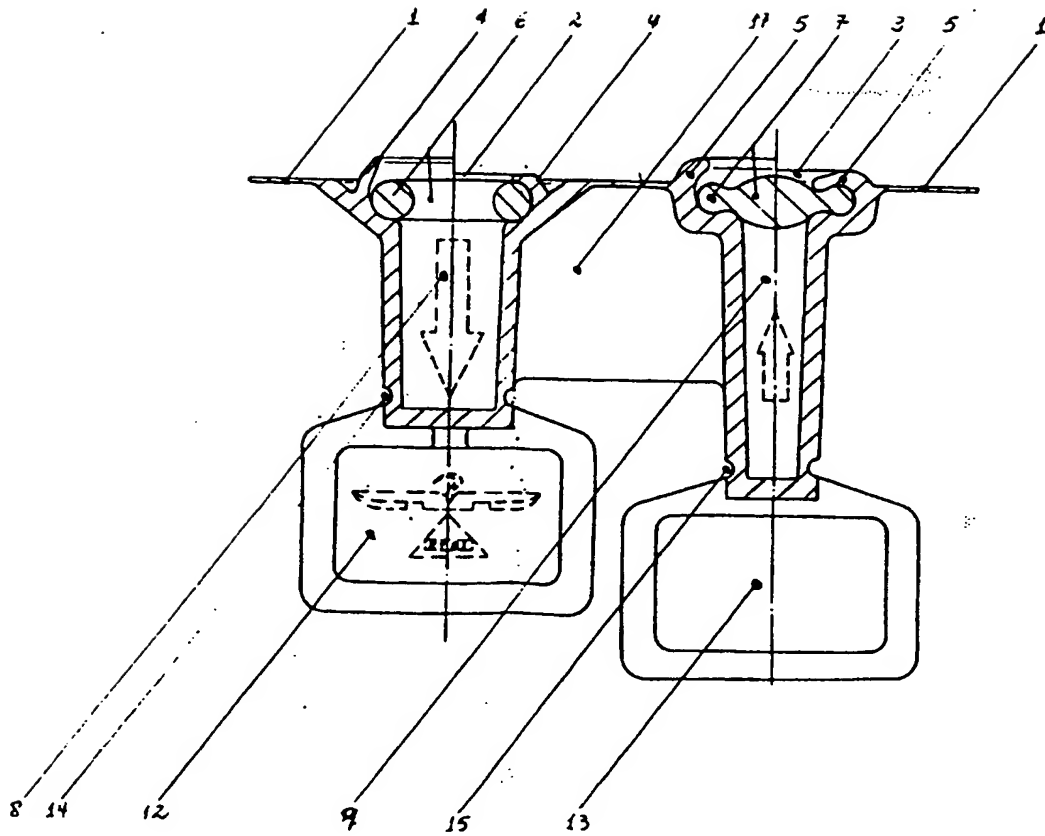


FIG. 3

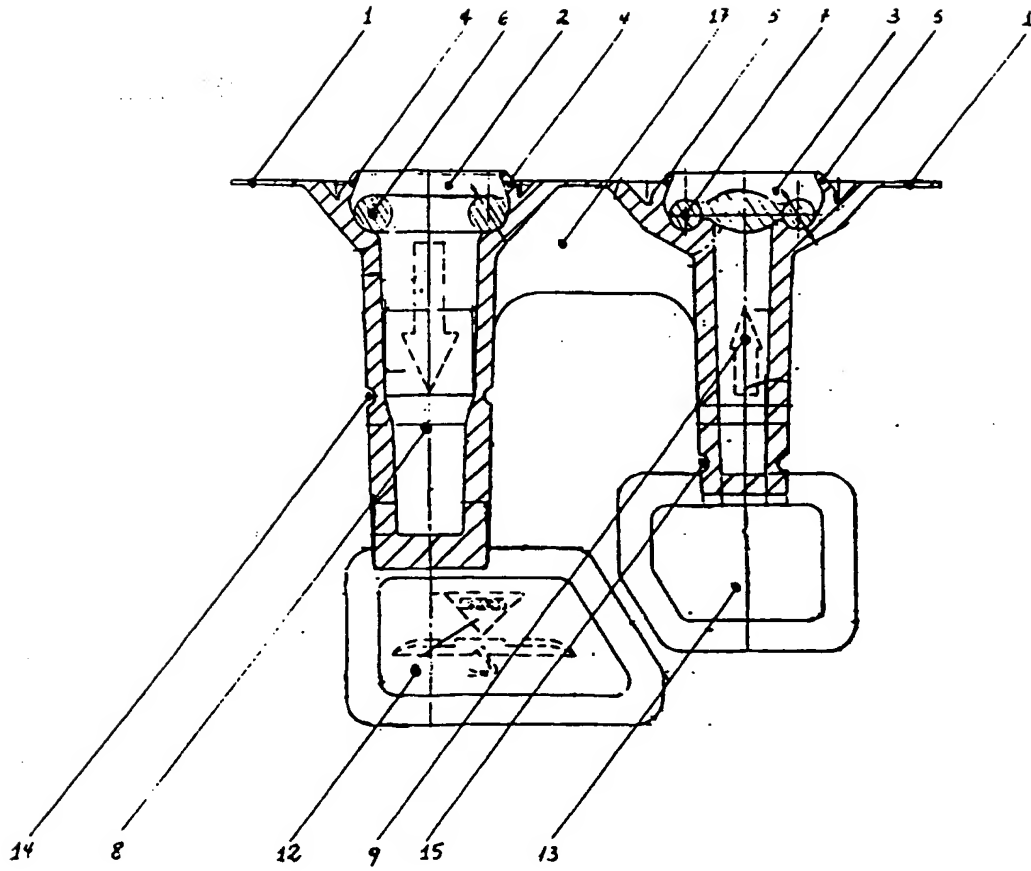


FIG. 4

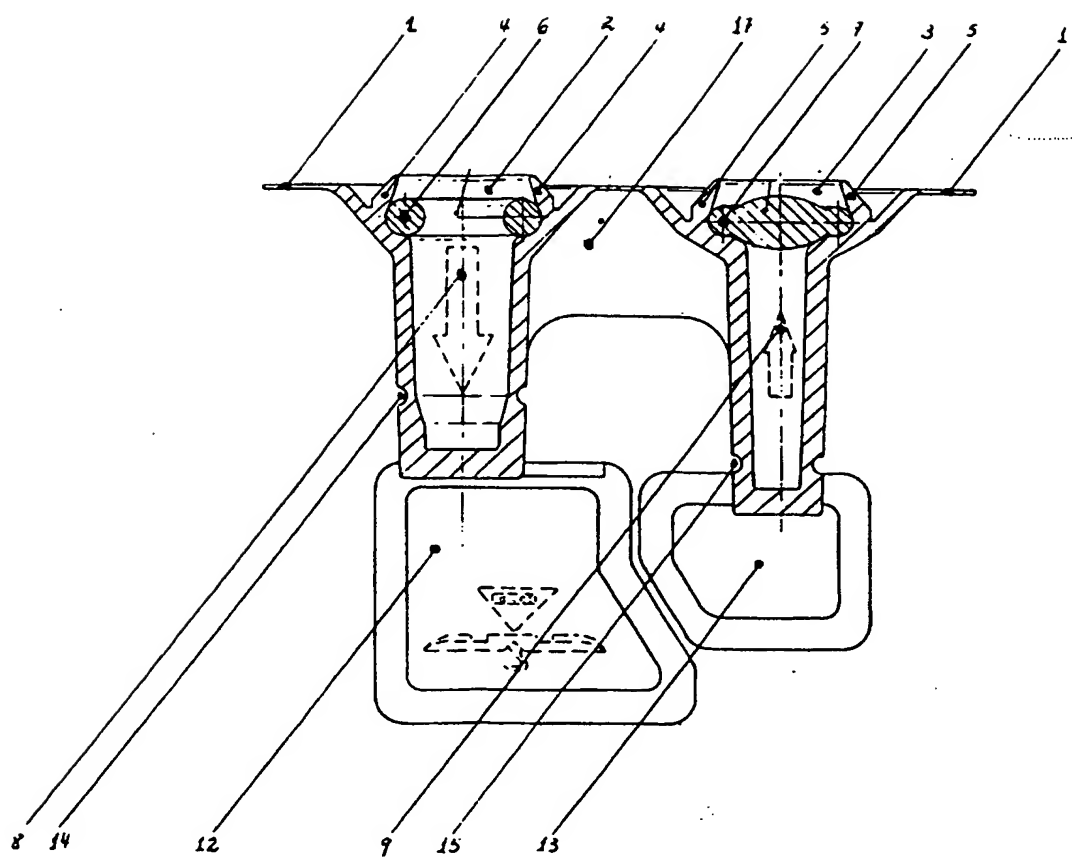


FIG. 5

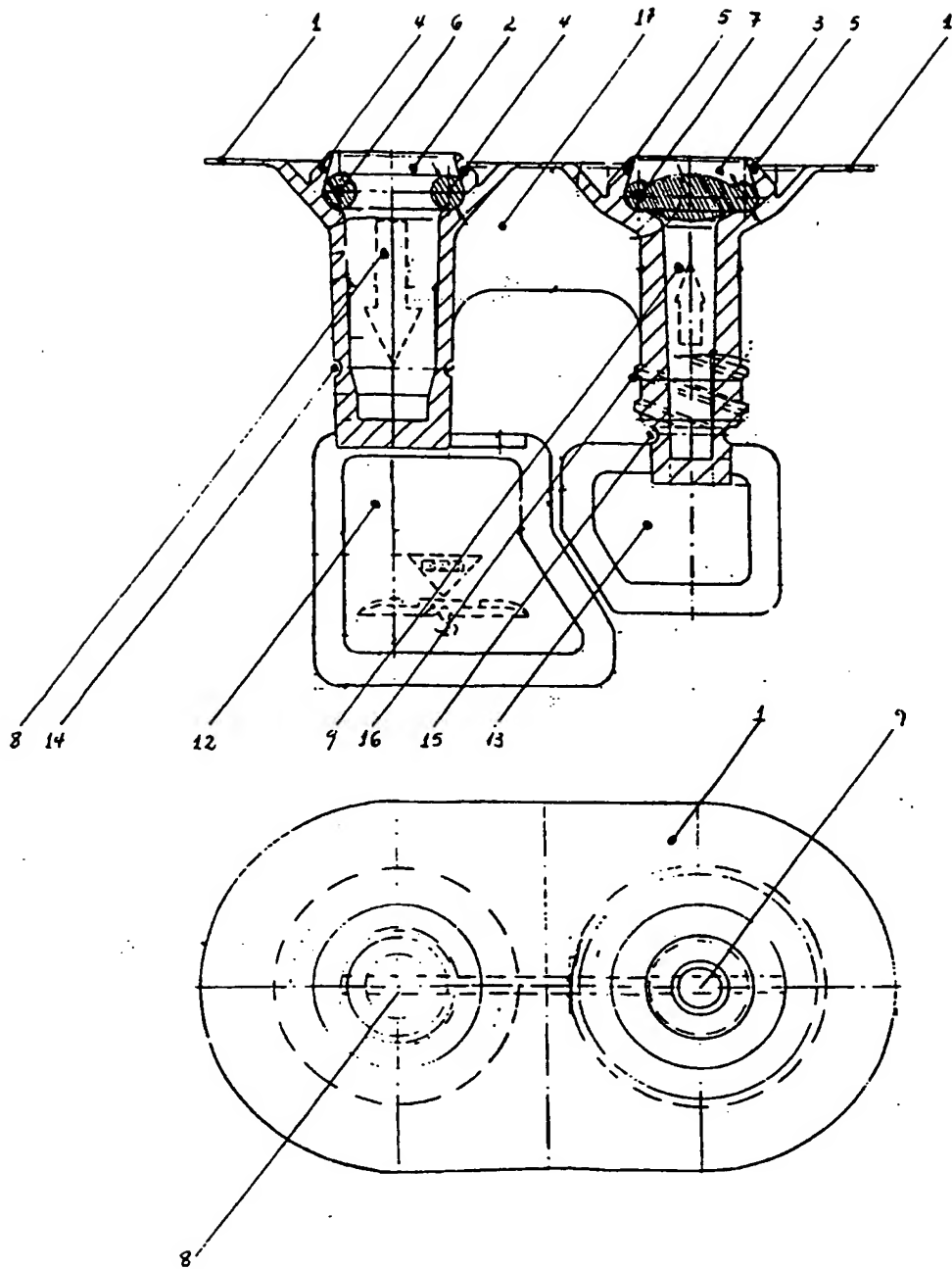


FIG. 6

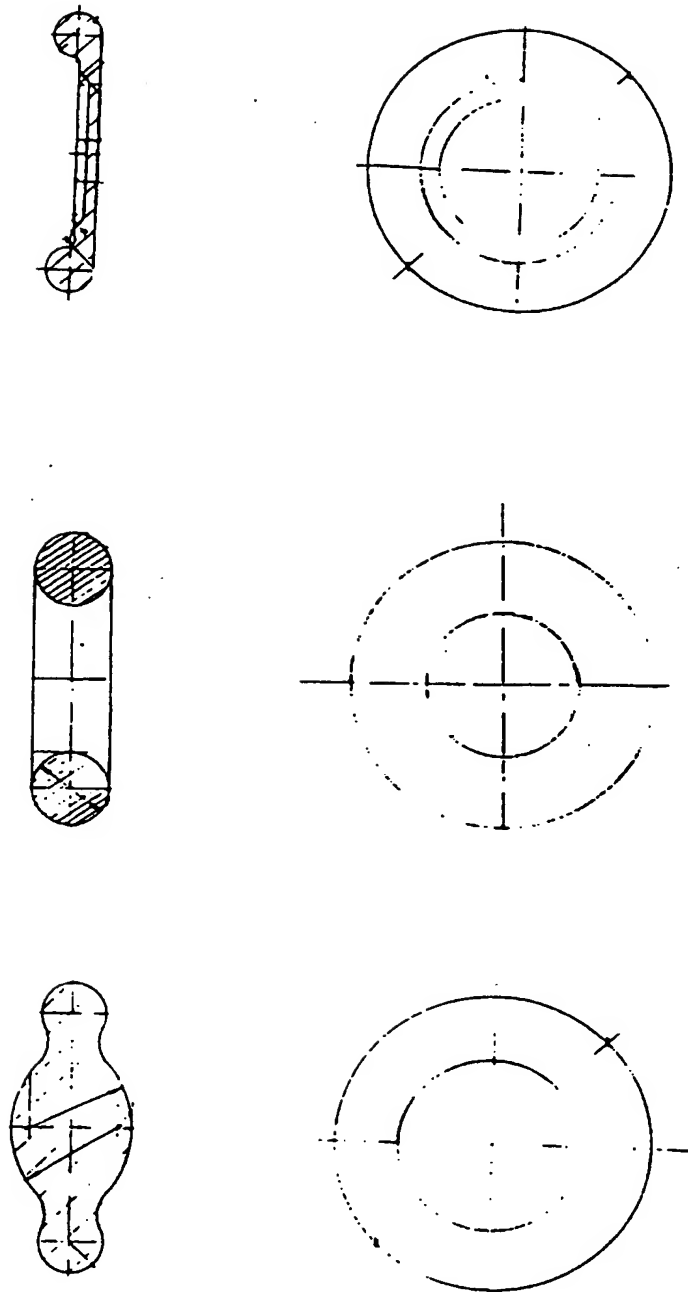


FIG. 7

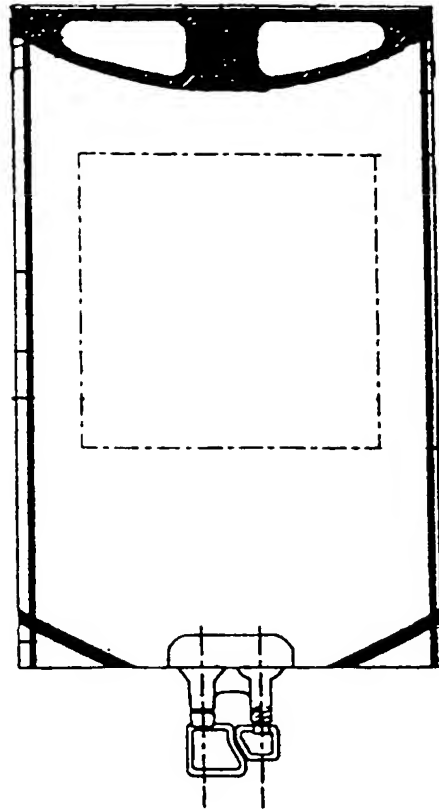


FIG. 8



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 50 0092

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US-A-4 892 222 (BAXTER INTERNATIONAL INC.) * column 3, line 15 - line 23 * * column 3, line 64 - line 68 * * column 4, line 1 - line 25 * * column 4, line 39 - line 62; figures *	1-3	A61J1/14
X	WO-A-8 906 553 (BAXTER INTERNATIONAL INC.) * page 18, line 28 - line 38 * * page 19, line 9 - line 23 * * page 21, line 30 - line 38 * * page 22, line 1 - line 24; figures 9,12,13,24-27 *	1,7	
Y	GB-A-2 160 184 (DRG LIMITED)	1	
A	* the whole document *	2-4,6	
Y	GB-A-2 203 118 (FUSO PHARMACEUTICAL INDUSTRIES LTD.) * page 3, line 19 - page 4, line 23; figures 2,3 *	1	
A	DE-U-8 910 550 (PFRIMMER KABI GMBH & CO KG) * page 4, line 22 - page 6, line 25; figures *	2-4,6	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A61J
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 23 APRIL 1992	Examiner BAERT F.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 150 (04/92) (P0601)